UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JOHN HANCOCK LIFE INSURANCE COMPANY, JOHN HANCOCK VARIABLE LIFE INSURANCE COMPANY, and MANULIFE INSURANCE COMPANY (f/k/a INVESTORS PARTNER INSURANCE COMPANY), Plaintiffs, v. ABBOTT LABORATORIES, Defendants.	CIVIL ACTION NO. 05-11150-DPW Hon. Judge Douglas P. Woodlock

ABBOTT'S TRIAL BRIEF

By the time Abbott and Hancock entered into the Research Funding Agreement ("RFA" or "Agreement"), Abbott had spent over a half billion dollars to research and develop the nine Program Compounds that are included in the Agreement and planned to spend more than $1 billion of its own funds over the next four years continuing to develop them. Hancock was well aware from the start, due to its own due diligence and disclosures by Abbott, that most developmental drugs are terminated for scientific or commercial reasons before reaching the market, and that many of the Program Compounds were particularly risky because they were novel compounds in early stages of development. Despite that knowledge, Hancock chose to enter into the RFA. Now, having freely made what it knew to be a risky investment, Hancock asks this Court to undo its decision through rescission, or to give it a windfall award of speculative lost profits, because it is unhappy with the outcome. The Court should reject this request.

Hancock alleges that Abbott committed fraud and breached the representations and warranties provision of the RFA by failing to disclose material adverse information about three of the Program Compounds. These allegations are meritless. As discussed in detail below, the evidence will show that, without exception, the allegedly omitted information was either disclosed to Hancock or was not material.

Even if Hancock could show any material misrepresentations, which it cannot, Hancock is not entitled to the speculative lost profits that it claims. Under Illinois's new business/new products rule, Hancock cannot recover lost profits from new products because such an award is inherently speculative. The evidence will show that the compounds at issue were all novel developmental compounds that had not received regulatory approval, thus there is no sales history upon which to base an award of lost profits. In addition, Hancock's claim for rescission is barred under the doctrines of waiver and judicial estoppel because for years after knowledge of the alleged misrepresentations, Hancock delayed seeking rescission and obtained a final judgment in *Hancock I* enforcing and affirming the Agreement.

The evidence will also show that Hancock cannot prevail on its other claims, including those alleging: (a) failure to spend the Section 3.3(b) Aggregate Carryover Amount, (b) misrepresentation of intended and reasonably expected spending in the Annual Research Plans, (c) breach of the out-licensing provisions, and (d) breach of the RFA's audit provisions.

ARGUMENT

I. ABBOTT DID NOT MAKE ANY MATERIAL MISREPRESENTATIONS OR OMISSIONS

A. Abbott Did Not Make Material Misrepresentations Regarding ABT-518

ABT-518 was part of a novel class of compounds called Matrix Metalloproteinase Inhibitors ("MMPIs") that were intended to inhibit the growth of cancerous tumors. (Abbott's

Prop. Add'l & Subs. Findings of Fact ("ASF"), ¶ 66.) Hancock alleges that Abbott decided to "stop all development activities on ABT-518" the week before the RFA was signed. (Hancock's Prelim. Prop. Findings of Fact ("HFF"), ¶¶ 72(c)-(e).) Hancock acknowledges that Abbott quickly reversed that decision, but implies that this reversal was a ruse to get Hancock to close the deal. (*Id.*, ¶¶ 72(f)(g), 76-79.) Hancock also claims that, although Abbott's "purported reason" for resuming development was to allow Abbott to review clinical data regarding other MMPI compounds that was to be released at the American Society of Clinical Oncology ("ASCO") meeting on May 12-15, 2001, Abbott made a "renewed decision" to end the program in early May based on the same information that was available in March. (*Id.*, ¶¶ 76-78.)

The evidence will show that Hancock's allegations are unfounded. From March 7-9, 2001, Abbott's senior management held a Portfolio Review Meeting to review all compounds under development. (ASF, ¶ 72(b).) Dr. Perry Nisen, the head of Abbott's oncology program, gave a presentation regarding ABT-518. (*Id.*) As reflected in the presentation, Abbott believed ABT-518 had potential advantages over competitor MMPI compounds. (*Id.*) As disclosed to Hancock in the RFA, however, it was not yet known whether ABT-518, in fact, would be able to demonstrate those advantages. (*Id.*, ¶¶ 68, 70, 72(b).) If problems experienced by competitor compounds were unique to those compounds and were not class-wide effects, Abbott would have a competitive advantage. (*Id.*, ¶ 72(b).) As Dr. Jeffrey Leiden, former Abbott Senior Vice President and Chief Scientific Officer, and Dr. John Leonard, Abbott's Corporate Vice-President of Global Medical and Scientific Affairs, will testify, Abbott could not draw any conclusions from the publicly available information regarding competitor compounds; it needed the clinical data that was to be presented at the ASCO conference scheduled for May 12-15, 2001. (*Id.*)[1]

[1] Furthermore, the RFA expressly provides that Abbott was not required to disclose "generally available information regarding the pharmaceutical industry in general." (ASF, ¶ 60.)

Dr. Leiden will testify that, after the Portfolio Review, he initially decided to temporarily halt enrollment in the Phase I ABT-518 clinical trial, which was just starting, while awaiting the ASCO data.[2] (*Id.*, ¶ 72(c).) Within days, Dr. Leonard and Dr. Nisen met with him to express their disagreement with his decision. (*Id.*, ¶¶ 72(c), (f).) Dr. Leonard will testify that he and Dr. Nisen reiterated their belief that ABT-518 had the potential to distinguish itself from the competition. (*Id.*, ¶ 72(f).) They noted that the costs Abbott would save by waiting a few months for the ASCO results were outweighed by the disadvantage of falling behind competitors. (*Id.*) Dr. Leiden will testify that he was persuaded by these arguments, and that he told Dr. Leiden and Dr. Nisen that the hold should be lifted. (*Id.*, ¶¶ 72(f)-(g).) The clinical trial was resumed shortly thereafter and the brief temporary hold had no impact on ABT-518's development. (*Id.*, ¶¶ 72(g), 73.)

Abbott's decision to lift the hold was not, as Hancock implies, a ruse to induce Hancock to finalize the deal. Dr. Leonard will explain that he emphasized to Dr. Leiden the scientific and commercial reasons for lifting the hold. (*Id.*, ¶¶ 72(f)-(g).) Dr. Leonard mentioned the upcoming RFA only to remind Dr. Leiden that Abbott had additional funds to invest in ABT-518, which would improve the compound's risk profile. (*Id.*) In any event, as Dr. Leiden will testify, the Agreement with Hancock played no role in his decision to lift the hold. (*Id.*) An email from Phil Deemer, Abbott's director of Business Development and Licensing, that Hancock cites to support its "ruse" theory actually undercuts it. Although Mr. Deemer expressed

[2] One version of an "Initial Portfolio Prioritization" document prepared by McKinsey & Company states that the initial decision was to "Hold" the trial, which is consistent with the recollections of Dr. Leiden and others who attended the meeting. (*Id.*, ¶ 72(c).) Another version of the document contradictorily states "Hold/[T]erminate," rather than "Hold", a discrepancy that Jessica Hopfield, the McKinsey consultant, could not explain. (*Id.*) In any event both versions state "[w]ait for May results from Pfizer" at the ASCO conference in "May" in order to "save ~ $1 mill" in clinical trial costs and then "re-evaluate." To that extent, the documents are consistent with the recollections of those who attended the meeting. (*Id.*)

concern about the *potential* impact on the Hancock deal *if* in fact ABT-518 was being "slowed down," he then observed that ABT-518 "*is back on track.*" (*Id.*, ¶ 86.) That observation is consistent with the evidence, which shows that the clinical trial hold was very brief and had no material impact on the compound. (*Id.*, ¶¶ 72(g), 73, 74.)

The ASCO conference was held on May 12-15, 2001. (*Id.*, ¶ 76.) As Dr. Leiden and Dr. Leonard will testify, Abbott obtained for the first time at the ASCO conference the detailed clinical and scientific data that was necessary to make a decision about whether the development of ABT-518 should proceed. (*Id.*) On May 28, 2001, Dr. Leiden attended a presentation by Dr. Nisen and other members of the ABT-518 team regarding clinical data obtained at the conference. (*Id.*) Based on that data, Abbott senior management decided, shortly after the May 28 presentation, that Abbott should not proceed with further development of ABT-518. (*Id.*)[3]

B. Abbott Did Not Make Any Material Misrepresentations Or Omissions Regarding Its ABT-594 Program

1. Abbott Disclosed the Material Information Regarding Nausea and Vomiting Side Effects of ABT-594

Hancock alleges that Abbott failed to disclose the nausea and vomiting adverse events experienced by patients in clinical trials of ABT-594. In the RFA, however, Abbott expressly warned that ABT-594 had a "Low" probability of achieving its target profile of "Low nausea/vomiting." (ASF, ¶ 95.) Abbott provided Hancock with the rates of adverse events, including nausea, headache, dizziness, insomnia, and vomiting, experienced by patients in clinical trials. (*Id.*) Dr. Lynn Klotz, Hancock's independent scientific expert who conducted due

[3] Hancock alleges that an unexplained, single-word reference to "Terminate" in a McKinsey document shows that Abbott made a "renewed decision" to discontinue development of ABT-518 at a May 5-6, 2001 strategy review, prior to the ASCO conference. (Pltfs.' Prelim. Prop. Findings of Fact ("HFF") ¶¶ 76-78.) However, Ms. Hopfield's testimony does not support Hancock's contention and Dr. Leiden, who chaired the May 5-6 meeting, will explain that there was no discussion at that meeting regarding termination of ABT-518. *Id.* If Abbott had decided to terminate ABT-518 at the May 5-6, 2001 meeting, there would have been no reason for senior management to analyze the ASCO results as it did.

diligence on the Program Compounds, acknowledged at his deposition that Abbott's disclosures were sufficient to raise a "red flag." (*Id.*, ¶ 97.) Dr. Klotz specifically warned Hancock that the therapeutic window (*i.e.*, the ratio between the maximum tolerated dose and minimum efficacious dose) could be "too narrow" and that there was "some risk of not passing phase II clinical trials." (*Id.*) Abbott also expressly disclosed that ABT-594 might be terminated as early as June 2001 based on the results of the pending Phase IIb trial. (*Id.*, ¶ 95.)

2. Abbott Did Not Have Material Concerns Regarding the Number of Premature Terminations Of Patients In the Phase IIb Trial

In April 2000, Abbott began its Phase IIb study of ABT-594 in patients with diabetic neuropathic pain. (ASF, ¶ 98(a).) As disclosed to Hancock, an earlier Phase IIa trial indicated a trend toward efficacy at 75 micrograms, but also significant levels of adverse events, such as nausea, vomiting, and headaches. (*Id.*, ¶ 95.) The Phase IIb study was designed to determine whether there was a dose at which patients would experience efficacy without adverse events. (*Id.*, ¶ 98(a).) Patients were divided into four treatment groups, three of which were given different doses of ABT-594 (150, 225, and 300 micrograms) and one of which was given a placebo. (*Id.*) The study was double-blinded, meaning that neither Abbott, the investigating physician nor the patient knew the treatment group to which the patients had been assigned. (*Id.*)

As the ABT-594 medical director, Dr. Bruce McCarthy, testified, although there were drop-outs from the study, that was neither unusual, unexpected, or, for those people managing the program or making executive decisions, cause for significant concern. (*Id.*, ¶¶ 98(a)-(f),(j).) It had been anticipated that there would be drop-outs from adverse events at the higher dosages; those doses had been selected specifically to determine the maximum tolerable dose. (*Id.*, ¶¶ 98(a),(c).) As the evidence will show, since the study was double-blinded, Abbott could not determine the correlation between drop-outs and various doses of ABT-594 until the data was

unblinded in April 2001. (*Id.*, ¶¶ 98(a)-(d),(f).) While a few documents from Summer 2000 reference "concern" regarding dropouts, those concerns relate only to the potential impact on the enrollment "goal" of 320 patients, not the results of the study. (*Id.*, ¶ 98(j).) Moreover, by December 2000, any such concerns were moot because Abbott had enrolled a sufficient number of patients to have a statistically valid study and to achieve the scientific goals of the study. (*Id.*)

3. Abbott Did Not "Prematurely Terminate" Its Phase IIb Trial

Abbott witnesses will testify that Abbott merely closed enrollment with 269 patients instead of 320, *so that it could continue the study to completion* without delaying its development schedule. (ASF, ¶¶ 98(g)-(k).) Abbott made the decision to end enrollment only after consulting with its statisticians and concluding that it could achieve a statistically valid result with fewer than 320 patients. (*Id.*) This decision was validated by Abbott's statistician, Mr. James Thomas, who will testify by deposition, and by Abbott's statistical expert, Dr. Bruce Rodda, each of whom has confirmed that Abbott obtained statistically significant results from the trial. (*Id.*, ¶ 98(h).) Abbott continued the trial until completion in April 2001. (*Id.*, ¶¶ 98(a), (c)(h).)

4. Abbott Did Not Make Any Significant Cuts To Its Planned Spending On ABT-594 Or Materially Delay Clinical Trials

Hancock claims that Abbott made a material misrepresentation by not updating the final draft of the Annual Research Plan ("ARP"), which is attached to the RFA, to show a reduction in the ABT-594 2001 budget from $35 million to $9.3 million. (HFF, ¶ 98(o).) The evidence will show that this allegation is untrue: First, Hancock exaggerates the reduction in projected 2001 spending. As of the date of the RFA, Abbott had allotted an additional $5.6 million for spending after June 2001, assuming there was a "Go" decision, for a total of $14.9 million in 2001. (ASF, ¶ 96.) Second, the reduction in planned 2001 spending was more than offset by the planned increase in spending in later years. (*Id.*) At the time the RFA was executed, Abbott's planned

spending on ABT-594 for the entire 2001-05 period was $24.6 million *greater* than reported in the ARP. (*Id.*, ¶ 98(o).) Thus, the reduction for 2001 was immaterial. (*Id.*, ¶ 98(p).)

Hancock also alleges that "Abbott's reduced spending for 2001 . . . did not include any funding for the previously planned additional Phase II or Phase III trials. . . which were described in [an Abbott document] as having been 'Delayed'." (HFF, ¶ 98(o).) Abbott's documents, however, show that the Phase III trial was delayed only from October 2001 to April 2002, and that this delay was immaterial because it was not expected to affect Abbott's plans to file a new drug application ("NDA") with the FDA in September 2003. (ASF., ¶ 98(p).)

5. Abbott's Management Did Not Determine In March 2001 That It Would Probably Terminate ABT-594

Hancock alleges that Abbott's management reached a "collective consensus" at the March 7-9, 2001 Portfolio Review that ABT-594 was a "probable T[erminate]." (HFF, ¶ 98(u).) However, the Abbott executives who attended that meeting, including Drs. Leiden and Leonard, will testify that there was no such consensus reached at that meeting. (ASF, ¶¶ 98(s)-(u).)[4] There was no discussion of patient dropouts or adverse events in Phase IIb because no scientific conclusions were or could be drawn from such information until the study was unblinded. (*Id.*, ¶¶ 98(s),(u).)[5]

[4] The presentation at that meeting included the same information regarding adverse events in the completed Phase IIa trial as was disclosed to Hancock and noted "data from the Phase IIb trial would be available in May 2001." (*Id.*, ¶ 98(u).) The presentation also noted, as disclosed to Hancock, that Abbott would make a "Go/No Go" decision in June 2001, after release of the Phase IIb data. (*Id.*, ¶¶ 95, 98(u).)

[5] The "probable T[erminate]" comment cited by Hancock is in a document prepared by a McKinsey consultant who was not familiar with the compounds. (*Id.*, ¶ 41) The Abbott attendees of the meeting have all testified that there was no conclusion reached that Abbott would "probabl[y] T[erminate]" ABT-594. (*Id.*, ¶¶ 98(s)-(u).)

C. Abbott Accurately Described the Status and Prospects of ABT-773

1. Abbott Did Not Have Undisclosed Concerns Regarding Safety

Contrary to Hancock's allegations, there were no significant, unresolved issues concerning the safety of the anti-infective ABT-773 as of March 2001 with respect to QT prolongation or liver toxicity ("hepatotoxicity") among clinical trial subjects who took the compound. (HFF, ¶ 115(a).) It was public knowledge that the FDA was generally scrutinizing *all* new pharmaceutical compounds with respect to QT prolongation and hepatotoxicity, and that there had been QT and liver problems with other anti-infectives such as quinolones and macrolides. (ASF, ¶¶ 115(a)-(b).) As Dr. Stanley Bukozfer, who was the head of Abbott's Anti-Infectives Venture, will explain, at the time of the Agreement there was no material adverse data regarding QT or liver issues with respect to ABT-773, or any other factual basis to believe these issues were of concern for ketolides. (*Id.*) At a meeting in late 2000 to discuss general issues regarding QT prolongation and hepatoxicity, Abbott told the FDA that there was nothing significant in the data Abbott had obtained on ABT-773 from the 900-plus patients that had been treated in the Phase 1 and 2 trials. (*Id.*, ¶ 115(b).) The FDA did not disagree. (*Id.*)[6]

Preclinical tests had demonstrated some effect on the liver function at doses far above the expected dosing range, but this was typical and was not expected to have a material impact on ABT-773. (*Id.*, ¶¶ 115(a)-(b).) One early trial showed elevated liver function tests for some Japanese patients, but Abbott repeated the study and determined that the liver results were due to the high caloric diet of the patients, not to ABT-773. (*Id.*) The immateriality of such

[6] The situation with respect to the FDA changed dramatically in April 2001, after the RFA had been signed. (*Id.*, ¶¶ 116-117) In reviewing the application of another pharmaceutical company for approval of a competing ketolide, the FDA required a 20,000 patent study to demonstrate the safety of the drug and, for the first time, issued an advisory on potential safety issues for all ketolides. (*Id.*)

information is shown by the fact that Abbott's disclosure to Hancock of elevated liver function tests in some clinical patients in another study did not cause Hancock concern. (*Id.*, ¶ 109.)

Similarly, as Dr. Leonard and other Abbott scientists responsible for the ABT-773 program will testify, they did not believe at the time of the Agreement that ABT-773 was likely to have QT problems. The only data indicating QT prolongation for ABT-773 was at superphysiological doses (over 800 mg) as of March 2001, not normal dosages that would be prescribed for patients (150 mg). (*Id.*, ¶¶ 115(a)-(b).) Furthermore, macrolides, such as erythromycin and clarithromycin, remained on the market despite evidence of QT issues, and were widely prescribed and successful anti-infectives. (*Id.*)

2. Abbott Accurately Represented the Expected Dosing of ABT-773 To Hancock

Hancock alleges that Abbott misrepresented the expected dosing of ABT-773 by stating in the Descriptive Memorandum that dosing was "expected to be once-a-day." (HFF, ¶ 115(d).) This allegation is not only inaccurate, it is frivolous.[7] Hancock claims the representation was misleading because Abbott did not disclose that it "still needed data from an ongoing Phase III trial before it could determine whether 150 mg, once-a-day dosing might be viable for two of the four target indications." (HFF, ¶ 115(d).) Abbott *expressly* disclosed in the RFA, however, that 150 mg, once-a-day dosing might not be viable for all indications, noting in the ARP that dosing would be "150 mg QD [once-a-day] or 150 mg BID [twice-a-day] depending on the severity of the indications." (ASF, ¶¶ 109, 112.) Hancock also alleges that Abbott should have disclosed that "300 mg, once-a-day dosing of ABT-773 'was not viable' for any indication." (HFF,

[7] Hancock did not include allegations regarding ABT-773's dosing or pediatric program in its first three complaints or its interrogatory responses. After discovery closed, and long after it had knowledge of the facts underlying these allegations, Hancock belatedly supplemented its interrogatory response to include these new claims. After summary judgment briefing, the Court ruled that Hancock could file an amended complaint containing the new allegations, but that Abbott could move to strike them. Abbott's motion to strike is fully briefed. If the Court grants that motion, it will narrow the issues to be presented at trial.

¶ 115(d).) But Abbott never represented that ABT-773 would be offered at 300 mg, whether for once-a-day or twice-a-day dosing. (ASF, ¶ 109.) To the contrary, Abbott disclosed that dosing would be "150 mg QD [once-a-day] or 150 mg BID [twice-a-day.]" (*Id.*)

Abbott's representations in the RFA regarding expected dosing of ABT-773 were accurate. As of March 2001, Abbott expected it would achieve once-a-day dosing for the two less severe (and more commercially significant) indications, pharyngitis and chronic bronchitis. (*Id.*, ¶ 115(c).) Abbott was awaiting data from an ongoing Phase III trial that was expected to be released in the second quarter of 2001 before deciding whether 150 mg, once-a-day dosing would be viable for the two more severe indications, community acquired pneumonia ("CAP") and sinusitus (chronic sinus infection). (*Id.*, ¶ 115(d).)

3. Abbott Accurately Represented the Status of Its Pediatric Program

Hancock alleges that Abbott's statement in the Descriptive Memorandum that the "likely profile" of ABT-773 would include an "[o]ral suspension form[] enabling penetration into pediatrics" was materially misleading because it did not disclose that its "pediatric oral suspension program for ABT-773 was 'on hold' and unfunded as of early 2001." (HFF, ¶ 115(f).)[8] But Abbott made no representations regarding the timing of its pediatric program and it expressly disclosed in the ARP that it budgeted "$0" in 2001 for "Pediatric" and "Taste Testing Studies". (ASF, ¶ 109.) The ARP further disclosed that the indications for ABT-773 are "Adult Tablet" and "I.V." (*Id.*) Another section of the ARP again noted that the "[p]roduct will be available as tablet and IV formulation", with no mention of an oral suspension pediatric product. Hancock also alleges that Abbott "knew that development of a pediatric oral suspension formulation of ABT-773 would be 'very difficult'" because of bitterness observed in

[8] Hancock did not assert its pediatric allegations until after the close of discovery, long after it had knowledge of the facts. These claims are the subject of a pending motion to strike. *See supra*, 10 n.7.

taste tests. (HFF, ¶ 115(e).) That was immaterial, however, for the reasons noted above and because Abbott planned to modify its formulation to improve the taste. (ASF, ¶¶ 115(e)-(f).)

Finally, Hancock also alleges that "Abbott . . . knew that its inability to develop a pediatric formulation of ABT-773 could pose a significant regulatory hurdle" in the United States because of FDA rules. (HFF, ¶ 115(e).) As Jeanne Fox of Abbott's U.S. Regulatory Affairs will testify, FDA rules did not require companies to complete their pediatric program prior to filing for approval of an adult drug. (ASF, ¶ 114.) Generally, pediatric programs are initiated after a drug sponsor has acquired a significant amount of adult data. (*Id.*, ¶ 115(f).) As of the date of the RFA, Abbott was projecting spending $9 million on the ABT-773 pediatric program in 2002 and $21.5 million in 2003. (*Id.*) Abbott was not planning on filing with the FDA until 3Q2002, so starting a pediatric trial in 2002 would be sufficient. (*Id.*)

II. HANCOCK IS NOT ENTITLED TO RESCISSION AND ITS CLAIM FOR DAMAGES IS WHOLLY SPECULATIVE

A. Lost Profits

Hancock claims, based on the testimony of its expert, Alan Friedman, that it suffered damages of $238 to $368 million in lost profits (plus prejudgment interest) in connection with its net investment of $90 million in nine Program Compounds, due to Abbott's alleged misrepresentations with respect to ABT-518, ABT-594, and ABT-773. (Friedman Aff., ¶¶ 43, 58.) Hancock's damage claim is contrary to Illinois law, which absolutely bars recovery of lost profits for new, unmarketed products on the grounds that they are inherently speculative. (ASF, ¶ 179); Abbott's Add. and Subs. Concl. of Law ("ASC"), ¶ 8.) Mr. Friedman's damage analysis also fails to satisfy the requirement that damages must be proximately caused by the alleged wrong and calculated with reasonably certainty.

1. Hancock's Claim for Lost Profits Is Barred By The Illinois Rule That Lost Profits From A New Product Are Unrecoverable Because They Are Inherently Speculative

Under Illinois law, a party claiming damage "bears the burden of proving those damages to a reasonable degree of certainty" and speculative damages are not recoverable. (ASC, ¶ 8); (ASF, ¶ 179.) A corollary of this rule is that lost profits are not available for a new business or a new product of an existing business. (ASC, ¶ 8.) Even where a plaintiff has shown that the company has a record of success in previous endeavors, Illinois courts do not allow recovery of lost profits for a new product. (*Id.*)[9] As Avram Tucker, Abbott's damages expert, will testify, the speculative nature of Hancock's lost profits claim is evidenced by the fact that the estimated probabilities of regulatory approval for two of the compounds, ABT-518 and ABT-594, were far below 50%. ABT-773 had a higher probability of success as of the date of the RFA, but like any developmental drug, regulatory approval and market success were always uncertain. Given the inherently extremely risky nature of pharmaceutical product development, there is no reasonable certainty that any of these untested products would have earned any profit. (*Id.*)

Hancock attempts to evade the new product rule by relying on a "probability-weighted" lost profits analysis that is unprecedented in Illinois law. Mr. Friedman purports to discount the estimated lost profits by the estimated probability that the compounds would have succeeded in the absence of the allegedly misrepresented or omitted facts. Mr. Friedman's approach would effectively reverse long-standing Illinois law holding that lost profits must be proven with reasonable certainty and are not recoverable for new products. Plaintiffs would be able to simply

[9] Hancock does not fall within the exception to the new business/new product rule that applies when lost profits are based on the profit history of a "fungible" product that has been "sold for quite some time", such as a branded version of a generic pharmaceutical compound. *Stuart Park Assoc. Ltd. P'ship v. Ameritech. Pension Trust*, 846 F.Supp. 701, 715 (N.D. Ill. 1994), aff'd, 51 F.3d 1319 (7th Cir. 1995) (distinguishing *Milex Prods. v. Alra Labs., Inc.*, 603 N.E. 2d 1226, 1236-37 (Ill. Ct. App. 1992)). Here, the compounds were new, had never been marketed, and are not fungible with any marketed product.

circumvent the Illinois new business rule by simply calculating projected profits and discounting by a probability of success. There is no indication that the Illinois courts would take such an unprecedented step and the Court should refrain from making such dramatic new law.

2. Hancock Fails to Establish Proximate Cause And To Calculate Damages With Reasonable Certainty

Even if Hancock were entitled to lost profits (which it is not), a proper calculation of such profits would calculate the value of the compounds as of the date of the RFA "but for" the allegedly undisclosed negative facts, less the actual value of the compounds *as of the time of the RFA* in light of the negative facts. (ASF, ¶ 179.) Mr. Tucker will explain that Mr. Friedman does not properly calculate either the "but for" or the "actual" scenario. Mr. Friedman uses as his "but for" scenario Abbott's internal projections as of the date of the RFA. (*Id.*) However, Keith Hendricks, the Abbott executive responsible for the projections, will confirm that the projections accounted for *any adverse information* known to Abbott at the time. Therefore, Mr. Friedman's reliance on these projections to calculate what the value of the compounds would have been "but for" the allegedly undisclosed adverse facts is illogical. (*Id.*) As Mr. Hendricks and Mr. Tucker will also explain, although Abbott's risk-adjusted sales projections are useful for making prioritization decisions between compounds, they are not designed to, and do not, predict the actual results for any particular compound or group of compounds. Second, Mr. Friedman uses as his "actual" scenario the status of the compounds as of December 2005, which reflects diminution in value due to post-contractual developments unrelated to the alleged fraud. (*Id.*) Mr. Friedman makes no effort to determine the portion of the decrease proximately caused by the allegedly undisclosed material adverse information, as opposed to post-contractual events.

B. Hancock Is Not Entitled to Rescission

The doctrines of waiver and judicial estoppel bar Hancock's claim for rescission. (Abbott's Supp. Prop. FF & COL ("ASPF"), ¶¶ 1-64, 69-77.) Under Illinois law a party seeking rescission must promptly assert that right. (ASPF, ¶¶ 93-97.) Undue delay or affirmation of the agreement after knowledge of the alleged fraud defeats the right to rescission. (*Id.*) Hancock first knew about the alleged fraud in 2003 and admitted in a verified interrogatory response that it had knowledge of the alleged fraud regarding all three compounds by "Fall/Winter 2004" from documents produced in the audit and *Hancock I*. (*Id.*, ¶¶ 10-14.) Yet Hancock did not make a rescission claim until 2006, and in the meantime took actions affirming the RFA. (*Id.*, ¶¶ 21-55.) Hancock also obtained a final declaratory judgment in *Hancock I* enforcing the RFA and declaring it in "full force and effect," and is judicially estopped from now reversing its position and seeking to declare the RFA void. (*Id.*, ¶¶ 6-7, 69-77.) Hancock's rescission claim is also barred by the limitation of remedies provisions in the RFA, which preclude termination of the RFA and a refund of Hancock's Program Payments here. (*Id.*, ¶¶ 60-64, 78-90.)[10]

Even if Hancock's claim were not barred by waiver, judicial estoppel, and the limitations of remedies provisions, Hancock is not entitled to rescission. Rescission is an equitable remedy to which plaintiffs are never entitled as a matter of right. (ASC, ¶ 39.) A party seeking rescission must demonstrate both actual and reasonable reliance and the Court also should consider factors such as "materiality, due care, knowledge, and intent of the parties." (*Id.*) Hancock cannot show that the allegedly omitted adverse information was material and that it actually would not have entered into the deal but for the alleged misrepresentations. (ASF,

[10] On July 20, 2007, Abbott moved for summary judgment on Hancock's rescission claim, on the grounds of waiver, judicial estoppel, and the limitations of remedies provision of the RFA. That motion is fully briefed and argued and the parties have agreed that the Court may rule on a "case stated" basis. The Court has indicated that it is inclined to grant the motion. If the Court grants Abbott's motion for summary judgment, it will narrow the scope of issues for trial.

¶¶ 17, 19, 27, 30-31, 34-38, 90, 105, 129; ASC, ¶¶ 4, 5.) Given Hancock's disregard of disclosed risks and publicly available information, it cannot show that it exercised due care and reasonably relied upon the allegedly misrepresentations. Nor can it show that the alleged misrepresentations were the result of any wrongful intent on Abbott's part.

III. THE EVIDENCE DOES NOT SUPPORT HANCOCK'S REMAINING CLAIMS

A. Abbott Did Not Misrepresent Its Intent and Reasonable Expectation Regarding Future Spending in the Annual Research Plans

Hancock claims Abbott misrepresented its projected expenditures in the ARPs, including its ARP for 2002, because the "ARPs reflect Abbott's 'nominal' spending, as opposed to its 'expected' [*i.e.*, risk-adjusted or probability-weighted] spending." (HFF, ¶ 133.) However, the RFA does not require Abbott to report its risk-adjusted expected spending. (ASF, ¶ 133.) The RFA provides that the ARPs shall set forth "a reasonably and consistently detailed statement of the *objectives* . . . *and budget* for the Research Program" (ASF ¶ 131; RFA, § 1.6.) Nor did Abbott represent in Section 12.2(d) that the ARPs provided risk-adjusted spending; instead, Abbott stated that the ARPs set forth "projected milestones . . . and *projected costs* . . . based on reasonable assumptions, and represent the reasonable estimate of Abbott . . . and that *actual results may vary* from such projections." (ASF, ¶ 131, RFA, § 12.2(d) (emphasis added).)

Hancock relies on Section 3.4, which provides that "[i]f Abbott . . . does not reasonably demonstrate in its [ARP] its intent and reasonable expectation" to spend in excess of the Aggregate Spending Target, Hancock may terminate Program Payments for any succeeding Program Years. (*Id.*, ¶ 132; HFF, ¶ 132.) Hancock's attempt to stretch the phrase "intent and reasonable expectation" beyond its ordinary meaning to require reporting of risk-adjusted expected spending conflicts with Section 1.6, which specifically provides for reporting of Abbott's "budget," and Section 12.2(d), which provides that "actual results may vary" from the

"projected costs" in the ARP. (ASF, ¶¶ 131-33.) Furthermore, Mr. Hendricks will testify that, although Abbott calculates risk-adjusted expected spending for certain portfolio analysis purposes, those risk-adjusted figures do not represent what Abbott actually intends and reasonably expects to spend on any one compound or group of compounds. (*Id.*, ¶¶ 134-40.)

In any event, Hancock cannot show any damages from Abbott's failure to report risk-adjusted expected spending. (ASF, ¶ 140.) Hancock makes a conclusory allegation that "Abbott's actual intended and reasonably expected spending . . . as of the end of 2001, was less than $614 million," but provides absolutely no support for this assertion. (HFF, ¶ 135.)[11] This assertion is without any foundation. Mr. Tucker will present calculations showing that Abbott's risk-adjusted expected spending at the end of 2001 was well in excess of $614 million. (ASF, ¶¶ 139-40.) Therefore, even if Abbott had reported its risk-adjusted expected spending, Hancock would not have been excused from its Second Program Payment of $54 million. (*Id.*)

B. Hancock Cannot Recover Damages For Abbott's Alleged Failure to Spend the "Aggregate Carryover Amount" Pursuant to Section 3.3(b)

In *Hancock I*, Hancock was relieved of its obligation to make its third and fourth Program Payments, totaling $110 million, pursuant to Section 3.4, because Abbott reported in its 2003 ARP that it did not expect to spend in excess of $614 million. (ASF, ¶¶ 145, 147.) Hancock now alleges it is entitled to additional relief because Abbott did not increase its spending to make up the shortfall caused by Hancock's termination of Program Payments. (*Id.*, ¶¶ 141-54.) Hancock alleges that because Abbott -- after being deprived of the $110 million in expected funding from Hancock -- failed to spend $614 million, Section 3.3(b) requires it to pay Hancock

[11] Similarly, Mr. Blewitt makes the equivocal and unsupported assertion that if Abbott had reported its "actual 'intended and reasonably expected' spending plans. . . . in its various ARPs . . . including its ARP for 2002, *I believe* that John Hancock *quite possibly* would not have been required to make, and *I believe* that John Hancock *quite possibly* would not have made, its Second Program Payment in the amount of $54,000,000 in January 2003." (Blewitt Aff., ¶ 124 (emphasis added).)

one-third of the difference (the unspent "Aggregate Carryover Amount"). (*Id.*, ¶ 143)[12] Based on the language of the RFA, when read as a whole, as well as the parol evidence and Hancock's judicial admissions in *Hancock I*, Hancock is not entitled to relief under Section 3.3(b). (ASPF, ¶ 65-68, 128-163; ASF, ¶¶ 141-154.) Furthermore, under Illinois law, Section 3.3(b), as interpreted by Hancock, would constitute an invalid and unenforceable penalty for Abbott's failure to spend $614 million, not a reasonable estimate of damages. (ASPF, ¶¶ 140-163.)[13]

C. Abbott Complied With Its Audit Obligations Under the RFA

Hancock alleges that Abbott engaged in an "unlawful campaign to hinder, delay, and obstruct" a contractual compliance audit conducted by StoneTurn. (HFF, ¶¶ 155-66.) However, the testimony of Michelle Campbell, the Abbott paralegal who worked on the audit, as well as business records, will show that Abbott made great efforts to respond to Hancock's overbroad audit demands and fully complied with its obligations. (ASF, ¶¶ 155-160.) Abbott produced over 800 boxes of documents regarding the Research Program. (*Id.*, ¶ 160(c).) Furthermore, Hancock cannot show any damages from Abbott's alleged efforts to obstruct the audit.

D. Abbott Compiled With Its Contractual Obligations Regarding Out-Licensing

Hancock claims Abbott breached Section 4.3(d) by not out-licensing ABT-518 and ABT-594 after terminating their development. (HFF, ¶¶ 167-77.) However, the RFA states that "[t]he obligations of Abbott . . . are expressly conditioned upon the safety, efficacy and commercial feasibility of each Product, consistent with using Commercially Reasonable Efforts." (ASF, ¶ 167.) The RFA also provides that the license or divestiture "shall maximize the commercial

[12] Abbott's pending motion to dismiss Hancock's Section 3.3(b) claim is fully briefed and argued. The parties have agreed to resolution of that motion on a "case stated" basis and the Court has indicated that it intends to grant the motion. If the Court grants that motion it will narrow the scope of issues for trial.

[13] Hancock's claim for $33.0 million in damages is also flawed because it is based on an Abbott report that inadvertently underreported actual spending, rather than the corrected spending figures. (ASF, ¶¶ 146, 149.) Damages based on Abbott's corrected actual spending would be $28.2 million.

value . . . to both parties," not merely benefit Hancock, and that Abbott "shall not . . . sell . . . out-license or otherwise treat any Program Compounds . . . differently, as compared to other Abbott compounds or products, on account of any of John Hancock's rights hereunder." (*Id.*)

Abbott complied with its obligations with respect to out-licensing of ABT-518 and ABT-594. (ASF, ¶¶ 169-177.) Abbott's business records show that Abbott solicited a large number of companies regarding the potential out-licensing of ABT-518 but was unable to secure a deal despite its best efforts. With respect to ABT-594, only one potential licensee, Bayer Animal Health, ever expressed interest. (*Id.*, ¶ 176.) As Dr. Leonard will testify, it would not have been commercially reasonable for Abbott to out-license or divest ABT-594 to Bayer Animal Health or another pharmaceutical company, particularly for development as a drug for animal health, because Abbott was continuing to develop other pain compounds with the same mechanism of action for use in humans. (*Id.*) Furthermore, Hancock offers no evidence that Bayer Animal Health or any other company would have been interested in out-licensing or purchasing ABT-594 after receiving confidential information regarding the compound (including the negative results of the Phase IIb trial), what the terms of any such agreement would have been, or what royalty milestone or other payments, if any, Hancock would have received under any such agreement. (HFF, ¶¶ 167-177.) Therefore, Hancock has failed to establish the fact, or the amount, of damages from Abbott's alleged breach of its out-licensing allegations. (ASF, ¶ 177.)

E. Indemnification by Abbott (Count III)

Hancock asserts an indemnification claim pursuant to the RFA. (Pltfs.' Concl. of Law ("HCL"), ¶¶ 35-38.) Under Illinois law, however, indemnity provisions are generally construed to apply only to third party claims, not claims between parties to an agreement. (ASC, ¶ 36.) The plain language of the RFA shows that it was intended to cover only claims by third parties. (*Id.*, ¶¶ 35-38.) The RFA provides that after Hancock gives notice of a claimed right to

indemnification, (a) Abbott has "the right to participate in, and . . . to assume the defense" of the action; (b) Hancock must "cooperate fully with [Abbott] and its legal representatives in the investigation of any action, claim or liability covered by indemnification"; and (c) Abbott may approve settlement of any such action. (ASC, ¶ 35.) Those requirements would make no sense if the indemnity provision was intended to cover claims between the parties. (*Id.*)

CONCLUSION

The evidence to be presented at trial will show that Abbott fairly disclosed all material information regarding the Program Compounds and otherwise complied with its obligations under the Agreement, and that Hancock cannot prevail on its claims.

ABBOTT LABORATORIES

By its attorneys

/s/ Gregory D. Phillips
Gregory D. Phillips

Jeffrey I. Weinberger (Admitted Pro Hac Vice)
Gregory D. Phillips (Admitted Pro Hac Vice)
Eric J. Lorenzini (Admitted Pro Hac Vice)
Ozge Guzelsu (Admitted Pro Hac Vice)
MUNGER, TOLLES & OLSON LLP
355 South Grand Avenue, 35th Floor
Los Angeles, CA 90071
(213) 683-9100

and

Michael S. D'Orsi
Peter E. Gelhaar (BBO #188310)
Michael S. D'Orsi (BBO #566960)
DONNELLY, CONROY & GELHAAR LLP
1 Beacon St., 33rd Floor
Boston, Massachusetts 02108
(617) 720-2880

Dated: February 18, 2008

CERTIFICATE OF SERVICE

I hereby certify that this document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on February 18, 2008.

On this 18th day of February, 2008.

/s/ Eric J. Lorenzini